K091706

DENTSPLY

AUG 2 8 2009

**DENTSPLY International**
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

# 510(k) SUMMARY
# for
# Quattro Porcelain System

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: June 8, 2009

2. Device Name:
   - Proprietary Name: Quattro Porcelain System
   - Classification Name: Powder, Porcelain
   - CFR Number: 872.6660
   - Device Class: II
   - Product Code: EIH

3. Predicate Device:
   - Company: DENTSPLY International
   - Device: Finesses Low Fusing Porcelain System
   - 510(K) No.: K954761
   - Date Cleared: 11/02/1995

4. Description of Device:

The Quattro Porcelain System is an integrated porcelain system used for the fabrication of dental restorations using three major porcelain fabrication techniques: porcelain-fused-to-metal (PFM), pressed-to-metal (PTM), and pressed all-ceramic (AC). Quattro PFM and PTM are indicated for both anterior and posterior crowns and bridges. Quattro AC is indicated for anterior to pre-molar crowns, inlays and onlays, and veneers.

5. Indications for Use:
Quattro Porcelain System is indicated for:

1. PFM Applications: Single and multiple unit porcelain fused-to-metal fixed prosthodontic restorations.

2. PTM Applications: Single and multiple unit porcelain pressed-to-metal fixed prosthodontic restorations.

3. All-Ceramic Applications: Single unit anterior and posterior premolar metal-free fixed prosthodontic restorations, laminate veneers, inlays and onlays.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The Quattro Porcelain System is an integrated system that can be used for porcelain fused to metal (PFM), pressed to metal (PTM), and all-ceramic (AC) restorations. All of the components found in the Quattro Porcelain System have been used in legally marketed devices and/or were found safe for dental use. The Quattro veneering has been evaluated and passed biocompatibility testing for cytotoxicity, irritation, systemic toxicity, sensitization, oral irritation, and genotoxicity.

Non-Clinical Performance Data

The performance of the Quattro Porcelain System's two structural components, dentin and ingot porcelain are comparable to other legally marketed Ceramco porcelains commercially used and successful for PFM and PTM restorations.

Conclusion as to Substantial Equivalence

We believe that the prior use of the components of the Quattro Porcelain System in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of the Quattro Porcelain System for the indicated uses.

We believe that the test data and the predicate comparisons provided in the Quattro Porcelain System 510(k) application demonstrate that the device is as safe and as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 2 8 2009

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404-0872

Re: K091706
Trade/Device Name: Quattro Porcelain System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 8, 2009
Received: June 10, 2009

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

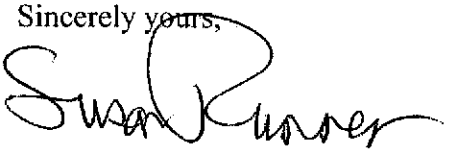
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091706

Device Name: Quattro Porcelain System

Indications for Use:

Quattro Porcelain System is indicated for:

1. PFM Applications: Single and multiple unit porcelain fused-to-metal fixed prosthodontic restorations.
2. PTM Applications: Single and multiple unit porcelain pressed-to-metal fixed prosthodontic restorations.
3. All-Ceramic Applications: Single unit anterior and posterior premolar metal-free fixed prosthodontic restorations, laminate veneers, inlays and onlays.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori Hurley for MSB

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091706